UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, DC 20231

SAH

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/493,442	06/22/95	ARTER T	CDS-59

12M1/0527

AUDLEY A CIAMPORCERO JR
ONE JOHNSON AND JOHNSON PLAZA
NEW BRUNSWICK NJ 08933-7003

EXAMINER	
GITOMER,R	
ART UNIT	**PAPER NUMBER**
1211	5

DATE MAILED: 05/27/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 08/493,442	Applicant(s) Arter et al.
	Examiner Ralph Gitomer	Group Art Unit 1211

☒ Responsive to communication(s) filed on *Apr 28, 1997*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is clos d** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *9-11 and 13-17* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *9-11 and 13-17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The IDS received 12/16/96 and the amendment received 4/28/97 have been entered and claims 9-11, 13-17 are currently pending in this application.

In view of the rewritten claims and arguments presented, the rejections under 35 U.S.C. § 112, second paragraph, and 102(b) are hereby withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11, 14, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Arter or Hammond in view of either Matsumoto or deCastro and in further view of Batz.

Arter (Clinical Chem dated July 1993) having different inventorship than this application, entitled "Development of a Multilayered Colorimetric Assay for Serum Acetaminophen," teaches in the abstract, a multilayered colorimetric assay using aryl acyl amidase to hydrolyze acetaminophen into p-aminophenol after application of serum to the slide. P-aminophenol formed is oxidized by either tyrosinase or by ascorbic acid oxidase so that it will form a dye with tetrahydroquinoline coupler. The dye is determined and is proportional to the amount of acetaminophen present.

Hammond (Analytical Biochemistry) entitled "Development of an Enzyme Based Assay for Acetaminophen" teaches on page 153 column 2, acetaminophen is enzymically hydrolyzed by aryl acylamide amidohydrolase to yield p-aminophenol and acetate. Then color reagents were studied with cyanoferrate complexes. On page 154 Table 1 teaches various color reactions and reagents.

The claims differ from Arter and Hammond in that they include a coupling agent with the color reagent and an oxidizing enzyme which couples to p-aminophenol, such as ascorbic acid oxidase, lactase and tyrosinase.

Matsumoto (4,675,290) entitled "Assaying Peptidase Enzyme Activity" teaches an assay for enzyme activity which comprises

reacting an amide compound with peptidase, and treating the liberated amine with a coupler, forming a colored pigment by means of oxidative condensation in the presence of an enzyme oxidant. The reaction scheme is as follows:

(1) Amide peptidase --> amine +

(2) Coupler Enzyme oxidant --> colored product.

In column 3 compound 4 a substrate for the enzyme, an amide, is shown which upon action of the peptidase yields an amine, compound 5. Compound 5 is converted to a chromogen by oxidative condensation of the coupler, compound 3 disclosed in column 4. The coupler is described as an aromatic compound which forms a chromogen having absorption maxima at 550-750 nm. The enzyme oxidants include ascorbate oxidase, tyrosinase in column 8 line 14. In column 8 line 49 through column 9 the aniline derivative forms a chromogen with a coupler, a cyanoferric compound. In column 10 first full paragraph, various cyanoferric complexes are shown.

deCastro (4,999,288) entitled Test Composition and Method for the Determination of Anilides" teaches determination of acetaminophen with stabilized arylacylamidase which cleaves the amide bond of acetaminophen, and reagents which act as oxidizing agents and accelerate color development.

The reaction scheme is as follows:

(1) Acetaminophen arylacylamidase --> 4-hydroxyaniline (amine)+

(2) Phenol derivative (coupler) catalyst/oxidant -->

colored product.

deCastro teaches periodate as the catalyst/oxidant which enables color formation to take place in one step so that all reagents can be added to the sample in one step which makes it possible to develop, dip and read test strips containing all the necessary reagents needed for testing an anilide.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oxidizing enzyme and coupling agents of Matsumoto and deCastro in the determination of Arter and Hammond because the reactions employed for the determinations are nearly identical and Matsumoto and deCastro provide motivation for employing coupling agents and oxidizing enzymes. To employ coupling agents to enhance color formation is well known in this art and is employed in the presently claimed invention for its art recognized function. Both Matsumoto and deCastro employ oxidizing agents and enzymes for the same function as presently claimed.

The present claims further differ from the above references in that they are directed to specific coupling agent compounds which encompass 1-(3-sulfopropyl)-1,2,3,4-tetrahydroquinoline.

Batz (4,845,030) entitled "Use of Aniline Derivatives As Coupling Components In Oxidative Color Formation Reactions" teaches in column 2, structure I which encompasses the presently claimed coupling agent, 1-(3-sulfopropyl)-1,2,3,4-tetrahydroquinoline. The aniline derivatives of Batz are shown

to have substantially improved color stability and a lower blank creep in oxidative coupling reactions. Substitutions with polar groups show an improved solubility and groups such as alkylsulfonic acid or sulfonic acid groups show good water solubility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific coupling agent of Batz in the determinations of Arter, Hammond, Matsumoto and deCastro because Matsumoto and deCastro teach closely related coupling agents for the same function as presently claimed. One would have a high expectation of success in substituting a known coupling agent for any of a large group of coupling agents in view of Batz because Batz teaches the presently claimed coupling agent for the same function as presently claimed.

Claims 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Arter or Hammond in view of either Matsumoto or deCastro and in further view of Batz as applied to claims 9-11, 14, 17 above, and further in view of Kawaguchi.

The teachings of Arter, Hammond, Matsumoto, deCastro and Batz and their applicability to the instant invention have been discussed above.

The claims differ from the above references in that the element contains maleimide in the spreading layer.

Kawaguchi (4,820,649) entitled "Method and Kit Having Layered Device for Detecting Biological Component by Interference Color" teaches in column 17 lines 22, column 18 first full paragraph, column 18 lines 32-33, maleimide groups are employed in layered detection devices and related to interferences.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the maleimide of Kawaguchi in the test strips of the above references because the maleimide would have its expected function, reducing interferences.

Applicant's arguments filed 4/28/97 have been fully considered but they are not persuasive.

Applicants argue that Arter does not teach ferricyanide and a coupler, Kawaguchi does not teach the claimed maleimide, Hammond teaches a different pH range than that claimed, Matsumoto does not teach a coupler, deCastro does not teach gelatin or ferricyanide, Batz does not teach dry analytical elements, coupler or ferricyanide. The present invention avoids the problem of gelatin hardening.

It is the examiner's position that each of the above references were cited to show the features discussed above. Arter teaches a dry element, Hammond teaches the present

reaction, Matsumoto teaches couplers and cyanoferric compounds, deCastro teaches oxidizing agents, Batz teaches coupling agents, Kawaguchi teaches maleimide. Applicant's failure to consider the references together is inappropriate in view of the fact that the rejection was made under 35 U.S.C. § 103, on the basis of what the combined teachings of the references would have suggested to one of ordinary skill in the relevant art, and not under 35 U.S.C. § 102, on the basis of anticipation by any of the individual references.

The present claims do not contain limitations regarding hardening of gelatin.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703) 308-0204. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Ralph Gitomer
Primary Examiner
Group 1211

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200